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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,014	02/08/2001	Fang Fang	019815-00020	8728

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,014	FANG, FANG	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-9, in Paper filed on 9/2/03; and species election of ICAM-1, filed on 11/24/03 are acknowledged.

2. Claims 10-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper filed on 9/2/03.

3. Claims 1-9 are currently being examined in this application.

4. Upon further consideration of the elected invention, the following restriction is required.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 8-9, drawn to a method of screening for peptide ligands of a target, wherein the complementary peptides contain complementary amino acids which are selected depending on their hydropathy.

Group II, claim(s) 1-9, drawn to a method of screening for peptide ligands of a target, wherein the complementary peptides are anti-sense peptides of said target protein.

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2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The different groups listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the different groups lack the same or corresponding special technical features for the following reasons:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity **and**

(B)(1) a common structure is preset, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The different inventions listed above are considered to be each separate inventions for the following reasons: It is noted that each of the groups have been presented in an improper Markush format, as distinct methods using improper Markush group of compounds. For example, complementary peptides (e.g., complementary amino acids of the target based on hydropathy, or anti-sense peptides), which are structurally and functionally distinct from each other and, as a result, has a different special technical feature. As the products and methods

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encompassed by the claims do not share a special technical feature, the distinct products and methods may not be properly presented in the alternative. Consequently, the special technical feature as defined by PCT Rule 13.2 has NOT been met because the requirements for both part (a) **and** part (b) above have NOT been met.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants have elected in the response filed on 11/24/03, the target protein is "ICAM-1".

The instant invention is drawn to a method of screening for peptide ligands of a target protein, and the method utilizes a collection of recombinant nucleic acids encoding complementary peptides. And the complementary peptides can be either complementary amino acids selected based on their hydrophathy or anti-sense peptides.

The species are as follows:

a) **Applicants are requested to provide the amino acid sequence or core sequence of the target peptide (ICAM-1); and the length of the target peptide, for the following reasons:**

The target sequence or core target sequence and the length is required because depending on the core sequence, the ligand peptide sequence would be different. i.e., The specification discloses complementary amino acids used in the claimed method, and for each single amino acid in the target peptide a vast number of different amino acids can replace one single amino acid, thus the ligand sequence differs based on the target amino acid sequence, and the length of target amino acids is required to determine the ligand sequence.

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b) Applicants are requested to elect the individual complementary amino acids used to replace the target peptide amino acid in the claimed method, for the following reasons.

If applicants elect complementary peptides are complementary amino acids which are selected based on the hydropathy score of amino acids, applicants are requested to provide core sequence of the target and each individual complementary amino acids used for each amino acid in the target sequence. The specification discloses complementary amino acids, and for each single amino acid there is a possibility of use of multiple individual amino acids. Thus one single amino acid, i.e., Gly can be replaced with either Thr, Trp, Ser, Tyr or Pro. Thus the use of different complementary amino acids would result in a different ligand, which would be structurally different from each other.

c) Applicants are requested to provide the target gene sequence, such that the anti-sense peptide encoded by the gene can be determined.

The target gene sequence is required to practice the claimed invention. Depending on the target sequence and the length the anti-sense strand of gene can be determined, such that the anti-sense amino acid sequence can be determined.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The different a) target sequences and b) peptide ligands based on hydropathy, and c) target gene sequence (such that the anti-sense peptides can be determined) listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2,

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the different groups lack the same or corresponding special technical features for the following reasons:

The different ligands, which are the result of use of different complementary amino acids or anti-sense peptides, or based on the target core sequence do not relate to a single general inventive concept under PCT Rule 13.2, because the species lack same or corresponding special technical feature for the following reasons: According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity **and**

(B)(1) a common structure is preset, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

In the instant invention the different target peptide sequence, complementary amino acids based on hydrophathy, and anti-sense peptides, represent an improper Markush format (i.e., no common structure and function). Consequently the special technical feature as defined by PCT Rule 13.2 has NOT been met because the requirements of both A) and B) above have not met.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

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the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Species a) claims 1-9;

Species b), claims 1-4, 8-9;

Species c) claims 1-9.

The following claim(s) are generic: 1-9.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Flex Schedule and can normally be reached Monday through Friday between 7 AM and 3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
04 March 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER